



DEPARTMENT OF COMMERCE

National Institutes of Standards and Technology

15 CFR Part 287

[Docket No.: 200813-0217]

RIN 0693-AB65

Guidance on Federal Conformity Assessment Activities

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Final rule.

SUMMARY: The National Institute of Standards and Technology (NIST) announces revisions to regulations updating guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment. The provisions are solely intended to be used as guidance for agencies in their use and reliance on conformity assessment to meet agency

requirements and do not preempt the agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or programmatic activities.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mr. Gordon Gillerman via email at 15CFR287@nist.gov, or by phone at (301) 975-4000.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Guidance

The guidance outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary complexity and make productive use of Federal resources, this guidance emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State, and local) and with those in the private sector. This guidance does not preempt agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or program activities. This guidance also does not preempt agency authority and responsibility in determining or implementing procurement, regulatory, or programmatic requirements.

II. Background

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 directs NIST to “coordinate technical standards activities and conformity assessment activities of Federal, State, and local governments with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the

development and promulgation of conformity assessment requirements and measures” (15 U.S.C. 272(b)(13)). NIST originally issued the guidance found in 15 CFR part 287 (this Guidance) on August 10, 2000, in response to Office of Management and Budget (OMB) Circular A-119 (February 10, 1998) directing the Secretary of Commerce to issue guidance to Federal agencies to ensure effective coordination of Federal conformity assessment activities (65 FR 48894). The January 2016 revision to OMB Circular A-119 re-emphasizes NIST’s role in issuing guidance to agencies as well as Federal agencies responsibilities with respect to conformity assessment. NIST is revising this guidance to reflect progression in conformity assessment concepts and evolution in Federal agency strategies and coordination in using and relying on conformity assessment.

This guidance is one of several activities undertaken by the NIST Standards Coordination Office to update its guidance, training, and other artifacts that help agencies develop and use conformity assessment. As a first activity, NIST provided significant input to the conformity assessment related policies of OMB Circular A-119. NIST released two NIST Special Publications (SPs) in September 2018. NIST SP 2000-01, *ABCs of Conformity Assessment*, serves as a primer for the topic of conformity assessment, and NIST SP 2000-02, *Conformity Assessment Considerations for Federal Agencies*, provides agencies with a path to follow in considering the development, use or improvement of conformity assessment to meet their requirements. The revisions to 15 CFR part 287 represent NIST’s most recent effort to provide Federal agencies with up-to-date tools for effective use of conformity assessment.

Summary of changes between the proposed rule and final rule

On February 7, 2020, NIST published a notice of proposed rulemaking (NPRM) in the Federal Register (85 FR 7258) requesting public comments on proposed revisions to regulations updating policy guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment. Nine (9) entities submitted comments, including two (2)

accreditation bodies, one (1) conformity assessment body, two (2) individuals, three (3) industry associations, and one (1) regional government. The following is a summary and analysis of the comments received during the public comment period, and NIST's responses including the recommendations and issues considered in the development of the CFR.

1. Comment: Commenters indicated that definitions should be updated to include new terminology and definitions for state agency, local agency, state standards executive, and local standards executive. In addition, commenters indicated changes to the definition of conformity assessment were necessary to ensure consistency between NIST conformity assessment publications and this guidance.

Response: NIST agrees with the need for consistency of definitions and has aligned the definitions in 15 CFR 287.2, Definitions, with those in OMB Circular A-119. NIST does not have the authority to define roles for a state standards executive or a local standards executive. The definition of NIST as an acronym has been removed from this guidance. During the rulemaking process, NIST realized this definition was unnecessary and that its removal does not result in substantive changes.

2. Comment: Commenters supported removal of examples (i.e., conformity assessment organizations by name and specific standards) from the NPRM. Other comments were received that support continued inclusion of examples.

Response: NIST reviewed the impact of the comments and has removed the examples. While they may be valuable as a learning vehicle, the use of examples may lead agencies to believe there are limited ways to address specific needs. In addition, the inclusion of some examples, (and exclusion of others) may be perceived as an endorsement or criticism by NIST.

3. Comment: Commenters responded that they were concerned changes reflected a reduction in NIST's role working with agencies and indicated that a central coordination role should be included to guide, collect, and disseminate Federal, State, and local conformity assessment activities.

Response: The roles and responsibilities of Federal agencies, including NIST, with respect to conformity assessment are stated in the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119. NIST does not interpret its statutory coordination role under the NTTAA with respect to State and local agencies to include the collection and dissemination of conformity assessment information from State and local agencies, as the explicit purpose of the relevant provision is limited to eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.

4. Comment: Commenters responded that greater emphasis was placed on the role of the Interagency Committee for Standards Policy (ICSP), including coordination of conformity assessment activities through this committee in the proposed revisions to the regulations than the original CFR.

Response: NIST has clarified language in 15 CFR 287.3(c) regarding the role of the ICSP by adding the phrase, “and other means,” so that the new provision will indicate that NIST intends to “work with agencies through the ICSP and other means to coordinate Federal, State and local conformity assessment activities with private sector conformity assessment activities.” NIST utilizes the ICSP to exchange information, provide direction to Federal agencies, and provide opportunities for coordination. The ICSP provides a conduit for sharing conformity assessment information across agencies.

5. Comment: Commenters requested the use of Federal agency viewpoints in the development of voluntary consensus standards related to conformity assessment. In addition, commenters indicated that the term “voluntary consensus conformity assessment related standards” is not defined and may cause industry confusion.

Response: NIST has revised 15 CFR 287.4(g) to clarify the role of agencies in development of voluntary consensus standards as well as development of voluntary consensus standards related to conformity assessment. In addition, NIST intends to revise the term “voluntary consensus

conformity assessment related standard” to “voluntary consensus standards related to conformity assessment.”

6. Comment: Commenters indicated that NIST should not extend the review period of the effectiveness of this guidance from three to five years. Commenters expressed the need for frequent review due to the complex and dynamic nature of conformity assessment in addition to transparency and openness.

Response: NIST has kept the proposed language and maintained the five-year review of the effectiveness of the guidance consistent with the review periodicity of OMB Circular A-119.

7. Comment: Commenters indicated a need for state and local government conformity assessment coordination in addition to coordination within the Federal government in 15 CFR 287.3, NIST Responsibilities, and 15 CFR 287.4, Federal Agency Responsibilities.

Response: NIST has retained the language as written in the CFR. The proposed language is consistent with the statutory authority in NTTAA as well as OMB Circular A-119. NIST does not have the authority to expand the role of other Federal agencies regarding coordination of state and local conformity assessment activities.

III. Applicability of This Guidance

This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results. “Agency” means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal Government although those branches may use this guidance to inform their own use of conformity assessment.

IV. Classification

Executive Order 12866

This rulemaking is not a significant regulatory action under Executive Order 12866.

Executive Order 13771

This rule is not subject to the requirements of Executive Order 13771, because its likely impact is *de minimis*.

Executive Order 13132

This rule does not contain policies with federalism implications as defined in Executive Order 13132.

Regulatory Flexibility Act

The Chief Counsel for Regulation for the Department of Commerce certified at the proposed rule stage to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this rule, if adopted, would not have a significant economic impact on a substantial number of small business entities. No comments were received on this certification, so no Final Regulatory Flexibility Analysis is required, and none has been prepared.

Paperwork Reduction Act

This rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an Environmental Impact Statement is required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 287

Conformity assessment, Procurement, Trade agreements, Voluntary standards.

For the reasons stated in the preamble, the National Institute of Standards and Technology revises 15 CFR part 287 to read as follows:

PART 287 – GUIDANCE ON FEDERAL CONFORMITY ASSESSMENT

Sec.

287.1 Purpose and scope of this part.

287.2 Definitions.

287.3 Responsibilities of the National Institute of Standards and Technology.

287.4 Responsibilities of Federal agencies.

287.5 Responsibilities of Agency Standards Executives.

Authority: 15 U.S.C. 272.

§ 287.1 Purpose and scope of this part.

(a) This part outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary complexity and make productive use of Federal resources, this part emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State, and local) and with those in the private sector.

(b) Using conformity assessment in a manner consistent with this part supports U.S. Government efforts to meet trade obligations and demonstrate good regulatory practices, which reduces unnecessary obstacles to international trade and improves market access for products and services.

(c) This part applies to all agencies which set policy for, manage, operate, or use conformity assessment. This part does not preempt the agencies' authority and responsibility to make decisions authorized by statute or required to meet regulatory, procurement, or programmatic objectives and requirements. These decision-making activities include: determining the level of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost, and availability of technology

and technical resources (where statutes permit) in establishing regulatory, procurement, and program requirements.

(d) Each agency retains broad discretion in its selection and use of conformity assessment activities and may elect not to use or recognize alternative conformity assessment approaches if the agency deems the alternatives to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Nothing contained in this part shall give any party any claim or cause of action against the Federal Government or any agency thereof. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory, procurement, or programmatic conformity assessment actions.

§ 287.2 Definitions.

For the purposes of this part:

Agency means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment. It does not include the legislative or judicial branches of the Federal Government.

Agency Standards Executive means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of Office of Management and Budget (OMB) Circular A-119 and the guidance in this part.

Conformity assessment is a demonstration, whether directly or indirectly, that specified requirements relating to a product, process, system, person, or body are fulfilled. Requirements for products, services, systems, persons, and organizations are those defined by law or regulation, by an agency in regulatory or

procurement actions, or an agency programmatic policy. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions. Conformity assessment related terminology and concepts, including a discussion of the value and benefits of conformity assessment, are contained in NIST Special Publication 2000-01, *ABCs of Conformity Assessment* (2018) found free of charge at: <https://doi.org/10.6028/NIST.SP.2000-01> and NIST Special Publication 2000-02, *Conformity Assessment Considerations for Federal Agencies*, found at: <https://doi.org/10.6028/NIST.SP.2000-02>. The definitions of conformity assessment related terminology included in these documents are based on voluntary consensus standards. See OMB Circular A-119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

§ 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Coordinate issues related to agency conformity assessment program development, use, and implementation and issue guidance, training material, and other material to assist Federal agencies in understanding and applying conformity assessment to meet their requirements. Material is available at <https://www.standards.gov>.

(b) Chair the Interagency Committee on Standards Policy (ICSP); encourage participation in the ICSP; as well as provide resource support to the ICSP and its working groups related to conformity assessment issues, as needed.

(c) Work with agencies through the ICSP and other means to coordinate Federal, State, and local conformity assessment activities with private sector conformity assessment activities.

(d) Participate in the development of voluntary consensus standards, recommendations, and guidelines related to conformity assessment to ensure that Federal viewpoints are represented.

(e) Increase awareness of the importance of public and private sector conformity assessment through development and publication of conformity assessment resources. Material is available at <https://www.standards.gov>.

(f) To the extent that resources are available and upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(g) Review, within five years from [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], the effectiveness of the guidance in this part and recommend modifications to the Secretary as needed.

§ 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part. Agencies may rely on NIST Special Publication 2000-02 *Conformity Assessment Considerations for Federal Agencies* found free of charge at <https://doi.org/10.6028/NIST.SP.2000-02>.

(b) Develop and implement conformity assessment in a manner that meets regulatory, procurement, and programmatic objectives; reduces unnecessary complexity for stakeholders; makes productive use of Federal resources; and meets international trade agreement obligations.

(c) Provide a rationale for its use of specified conformity assessment in rulemaking, procurement actions, and agency programs to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(d) Work with other Federal agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities.

(e) Consider leveraging the activities and results of other governmental agency and private sector programs in lieu of creating government-unique programs or to enhance the effectiveness of proposed new and existing conformity assessment.

(f) Give a preference for using voluntary consensus standards, guides, and recommendations related to conformity assessment in agency operations. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs. See OMB Circular A-119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

(g) Participate, as needed, representing agency and Federal viewpoints, in efforts to develop voluntary consensus standards, guideline, and recommendations related to conformity assessment.

(h) Participate, as needed, representing agency and Federal viewpoints in efforts designed to improve coordination among governmental and private sector conformity assessment activities.

(i) Work with NIST, other Federal agencies, ICSP members, and the private sector to coordinate U.S. conformity assessment needs, practices, and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international trade of U.S. products and services.

(j) Assign an Agency Standards Executive the responsibility for coordinating agency-wide implementation of the guidance in this part who is situated in the agency's organizational structure such that the Agency Standards Executive is kept regularly apprised of the agency's regulatory, procurement, and other mission-related activities, and has sufficient authority within the agency to ensure implementation of the guidance in this part.

§ 287.5 Responsibilities of Agency Standards Executives.

Each Agency Standards Executive should:

(a) Carry out the duties in OMB Circular A-119 related to conformity assessment activities.

(b) Encourage effective use of agency conformity assessment related resources.

(c) Provide ongoing assistance and policy guidance to the agency on significant issues in conformity assessment.

(d) Contribute to the development and dissemination of:

(1) Internal agency policies related to conformity assessment issues; and

(2) Agency positions on conformity assessment related issues that are in the public interest.

(e) Work with other parts of the agency to develop and implement improvements in agency conformity assessment activities.

(f) Participate in the Interagency Committee on Standards Policy (ICSP) as the agency representative and member.

(g) Promote agency participation in ICSP working groups related to conformity assessment issues, as needed.

(h) Encourage agency participation in efforts related to the development of voluntary consensus standards, recommendations, and guidelines related to conformity assessment consistent with agency missions, authorities, priorities, and resources.

(i) Establish an ongoing process for reviewing the agency's conformity assessment programs and identify areas where efficiencies can be achieved through coordination within the agency and among other agencies and private sector conformity assessment activities.

Kevin A. Kimball,
Chief of Staff.